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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,871	07/02/2001	Heather A. Bowen-Leaver	2870/485	1385

7590

04/23/2003

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/23/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,871

Applicant(s)

BOWEN-LEAVER ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11,13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11,13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 27, 2003 has been entered. Claims 1-3, 5-11, 13, 15, and 16 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-11, 13, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner finds the term "silicone component" vague and indefinite. The claim recites and specification defines that the silicone component "***comprises*** at least one volatile silicone oil". Applicants assert that the "silicone component" can be a volatile silicone oil itself or a mixture with other volatile and/or nonvolatile silicone oil, and argue that the distinction between the prior art and the instant invention is the absence of silicone surfactants. Examiner notes that the policy of the Office is that claim language must be interpreted as broadly as possible. The scope of the limitation "silicone component" as recited in the claim encompasses the presence of the prior art silicone

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surfactants such as those in Ribier (US 5834013), silica, or any silicone-containing substances. The metes and bounds of the scope of the claim is unclear.

The remaining claims are rejected as depending on indefinite base claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

I. Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonnet (U.S. Pat. No.6,120,778) in view of Claudelli (U.S. Pat. No. 4,026,818) and Wiegand et al. (US 2002/0034489 A1).

Simonnet teaches oil-in-water nanoemulsion based on silicone surfactants, wherein the oil globules have a mean size of less than 100 nm. See abstract; col. 2, lines 1 - 26. The reference teaches that the composition may be formulated into a gel form. See col. 5, lines 32 – 36. The oily phase of the emulsion may be mineral oils or volatile or nonvolatile silicone oils, and the oily phase may be in the range of 5 –40 % by weight of the emulsion. See col. 3, lines 33 – 37. The reference teaches that the weight ratio of the oily phase to the silicone surfactant should range from 2- to 10, wherein the surfactant is used in the amount ranging from 1-15 %, and most preferably 4-5 % by weight. See col. 3, lines 24 – 27. Simonnet teaches the process of producing the invention by high-pressure homogenization at a pressure greater than 10^8 Pa, or at 1500 bars with 7 passes, in col. 4, line 63 –col. 6, line 9.

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While Simonnet suggests a nanogel, the reference fails to teach "ringing" gel.

Claudelli teaches transparent ringing gels for cosmetic use, comprising mineral oil, water, and 5-9 percent by weight of (2 ethyl 1,3-dihydroxy) 2-propyl oleamide. See col. 1, lines 5 – 63. The reference teaches transparent gels are obtained due to the small particle size of the dispersed droplet, which allows rapid absorption on skin of active ingredients contained in the composition. The reference teaches using low ratios of emulsifier to oil could be achieved, which is less costly. The reference teaches that it is well known in the art that clear ringing gel appeal to consumers. See col. 1, lines 5-9.

Wiegand teaches microemulsion ringing gel comprising surfactant phase and an oil phase for cosmetic. See abstract. The reference teaches that the oil phase of the invention can include mineral oil, silicone oil, and mixtures thereof. See p 2, [0026]. The silicone oil suitable for the invention include volatile oils such as cyclomethicone. See p. 3, [0027]. The reference also teaches that it is conventional practice to employ volatile silicone oil for cosmetic purposes. See p. 6, [0072].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the nanoemulsion of Simonnet into a gel as motivated by Claudelli and Wiegand because of the expectation of successfully producing a transparent gel composition with large amount oil with enhanced penetration action of active components into the skin. The motivation to formulate a clear ringing gel is also obvious in view of Claudelli because of the expectation of the commercial success. Examiner views that the "difference in complex viscosity" at the

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recited oscillation stress is a resulting measurement of an obvious variation of the prior arts.

II. Claims 7-11, 13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonnet in view of Claudelli, and Wiegland, and Kakoki et al. (U.S. Pat. No. 5,162,377) ("Kakoki").

Simonnet, Claudelli, and Wiegland, discussed above, lack an explicit teaching of the shearing process of instant claims 7 and 8. As for claim 16, examiner notes that Simonnet teaches using 1-15 % by weight of silicone surfactant to form a nanoemulsion.

Kakoki teaches the process of making a transparent emulsion cosmetic composition by applying high-shearing treatment to the composition. In the reference high shearing force treatment is carried out by high-pressure homogenization using emulsifiers such as Microfluidizer which is used in the present invention, or Manthon Gaulin, under a pressure of 500 psi or more. See col. 4, line 44 – col. 5, line 23. The Examples 4-13 shows treating the emulsion compositions with Manthon Gaulin at least 5-10 times to obtain transparent aqueous compositions.

Given the teaching in the combined references that high-pressure homogenization process is used to produce a nanoemulsion, one of ordinary skill in the art at the time the invention was made to have would have known looked for prior arts such as Kakoki for specific types of homogenizer, and method steps to carry out the process to make the said composition, and treated the pre-emulsion with high shearing force to produce transparent compositions.

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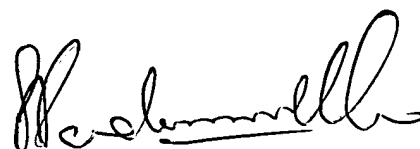
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
April 21, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

4/21/03